Package leaflet: Information for the user

Striroxin 25 microgram tablets
Striroxin 50 microgram tablets
Striroxin 75 microgram tablets
Striroxin 100 microgram tablets
Striroxin 125 microgram tablets
Striroxin 150 microgram tablets
Striroxin 175 microgram tablets
Striroxin 200 microgram tablets

levothyroxine sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What <invented name>is and what it is used for

Levothyroxine, the active substance in <invented name>, is a synthetic thyroid hormone for the treatment of diseases and dysfunctions of the thyroid gland. It has the same effect as the naturally occurring thyroid hormones.

<invented name>is used
- to treat benign goitre in patients with normal thyroid function,
- to prevent recurrence of goitre after surgery,
- to replace natural thyroid hormones, when your thyroid gland does not produce enough,
- to suppress tumour growth in patients with thyroid cancer.

<invented name>25 microgram, 50 microgram, 75 microgram and 100 microgram are also used to balance thyroid hormone levels, when overproduction of hormones is treated with antithyroid medicines.

<invented name>100 microgram, 150 microgram, and 200 microgram may also be used in the testing of your thyroid function. **
*** the respective information will only be included in the package leaflets of <invented name> 100 microgram, 150 microgram or 200 microgram.*

2. What you need to know before you take <invented name>

Do not take <invented name>
if you have any of the following:
- allergy (hypersensitivity) to the active substance or to any of the other ingredients of <invented name> (listed in section 6),
- untreated dysfunction of the adrenal gland, pituitary gland or excessive overproduction of thyroid hormones (thyreotoxicosis),
- acute heart disease (myocardial infarction or heart inflammation).

Do not take <invented name> together with antithyroid medicines if you are pregnant (see section Pregnancy and breast-feeding below).

Warnings and precautions
Talk to your doctor or pharmacist before taking <invented name> if you have any of the following heart diseases:
- insufficient blood flow in the blood vessels of the heart (angina pectoris),
- heart failure,
- rapid and irregular heart beat,
- high blood pressure,
- fatty deposits in your arteries (arteriosclerosis).

They must be under medical control **before** you start taking <invented name> or before a thyroid suppression test is performed. You **must** have frequent checks of your thyroid hormone levels while you are on <invented name>. If you are not sure whether any of these conditions applies to you, or if you do not receive treatment, contact your doctor.

Your doctor will investigate if you have a dysfunction of the adrenal or pituitary gland or a dysfunction of the thyroid gland with uncontrolled overproduction of thyroid hormones (thyroid autonomy), because this must be medically controlled before you start taking <invented name>or before a thyroid suppression test is performed.

Blood pressure will be regularly monitored when levothyroxine treatment is started in very low birth weight preterm neonates because rapid fall in blood pressure (known as circulatory collapse) may occur.

Thyroid imbalance may occur if you need to change your medication to another levothyroxine containing product. Talk to your doctor if you have any questions about changing your medication. A close monitoring (clinical and biological) is required during the transition period. You should tell your doctor if you get any side effects as this may indicate that your dose needs to be adjusted up or down.

Speak to your doctor,
- if you are in the menopause or post-menopausal; your doctor may need to check your thyroid function regularly because of the risk of osteoporosis.
- before you start or stop taking orlistat, or change the treatment with orlistat (medication to treat obesity; you may need closer monitoring and dose adjustment)
- if you experience signs of psychotic disorders (you may need closer monitoring and dose adjustment)

Thyroid hormones should not be used for weight reduction. Intake of thyroid hormones will not reduce your weight, if your thyroid hormone level is in a normal range. Serious or even life-threatening side effects may occur if you increase the dose without special advice from your doctor. High doses of thyroid hormones should not be taken together with certain medicines for weight reduction, such as amfepramone, cathine and phenylpropanolamine, as the risk of serious or even life-threatening side effects may increase.

If you are about to undergo laboratory testing for monitoring your thyroid hormone levels, you must inform your doctor and/or the laboratory personnel that you are taking or have recently taken biotin (also known as vitamin H, vitamin B7 or vitamin B8). Biotin may affect results of your

laboratory tests. Depending on the test, the results may be falsely high or falsely low due to biotin. Your doctor may ask you to stop taking biotin before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin. This could affect the results of laboratory tests. Please inform your doctor and/or the laboratory personnel, if you are taking such products (Please note the information in section Other medicines and <invented name>).

Other medicines and <invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, because <invented name>may influence their effect:
- Anti-diabetic medicines (blood-sugar-lowering medicines):
  <invented name>may **reduce** the effect of your anti-diabetic medicine, so you may need additional checks of your blood sugar levels, especially at the start of <invented name>treatment. While you are taking <invented name>, adjustment of the dose of your anti-diabetic medicine may be necessary.
- Coumarin derivatives (medicines used to prevent blood clotting):
  <invented name>may **intensify** the effect of these medicines, which may increase the risk of bleeding events, especially in elderly people. You may need regular checks of your blood clotting values, at the start of and during <invented name>treatment. While you are taking <invented name>, adjustment of the dose of your coumarin medicine may be necessary.

Make sure that you stick to the recommended time intervals, if you need to take any of the following medicines:
- Medicine used to bind bile acids and to lower high cholesterol (such as cholestyramine or cholestipol): Make sure that you take <invented name>4 - 5 hours **before** these medicines, because they may block the uptake of <invented name>from the intestine.
- Antacids (for the relief of acid indigestion), sucralfate (for ulcers of the stomach or intestine), other aluminium-containing medicines, iron-containing medicines, calcium-containing medicines:
  Make sure that you take <invented name>at least 2 hours before these medicines, because otherwise they may reduce the effect of <invented name>.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, because they may **reduce** the effect of <invented name>:
- propylthiouracil (antithyroid medicine),
- glucocorticoids (anti-allergic and anti-inflammatory medicines),
- beta-blockers (blood-pressure-lowering medicines also used to treat heart diseases),
- sertraline (antidepressive medicine),
- chloroquine, or proguanil (medicine to prevent or treat malaria),
- medicines activating certain liver enzymes such as barbiturates (sedatives, sleeping pill), carbamazepine (anti-epileptic medicine, also used to modify some types of pain and to control mood disorders) or products containing St. John’s Wort (an herbal medicinal product),
- oestrogen-containing medicines used for hormone replacement during and after the menopause or for prevention of pregnancy,
- sevelamer (phosphate binding drug, used to treat patients with chronic renal failure),
- tyrosine kinase inhibitors (anti-cancer and anti-inflammatory medicines).
- proton pump inhibitors (such as omeprazole, esomeprazole, pantoprazole, rabeprazole, and lanzoprazole) are used to reduce the amount of acid produced by the stomach, which may reduce the absorption of levothyroxine from the intestine and thereby make it less effective. If you are taking levothyroxine while receiving treatment with proton pump inhibitors, your doctor should monitor your thyroid function and may have to adjust the dose of <invented name>.
- orlistat (medicine to treat obesity)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the

following medicines, because they may **intensify** the effect of <invented name>:
- salicylates (medicine used to relief pain and to reduce fever),
- dicumarol (medicine to prevent blood clotting),
- furosemide in high doses of 250 mg (diuretic medicine),
- clofibrate (blood-lipid-lowering medicine).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, because they may influence the effect of <invented name>:
- ritonavir, indinavir, lopinavir (protease inhibitors, medicines to treat HIV infection),
- phenytoin (anti-epileptic medicine).

You may need regular checks of your thyroid hormone parameters. An adjustment of your dose of <invented name>may be necessary.

Tell your doctor, if you are taking amiodarone (medicine used to treat irregular heart beat), because this medicine may influence the function and activity of your thyroid gland.

If you need to have a diagnostic test or scan with iodine–containing contrast media, tell your doctor that you take <invented name>, because you may receive an injection that may influence your thyroid function.

If you are taking or have recently taken biotin, you must inform your doctor and/or the laboratory personnel when you are about to undergo laboratory testing for monitoring your thyroid hormone levels. Biotin may affect results of your laboratory tests (see warnings and precautions).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

<invented name>with food and drink
Tell your doctor, if you eat soy products, especially if you change the amount you eat. Soy-products may lower the uptake of <invented name>from the intestine and therefore, an adjustment of your <invented name>dose may be necessary.

Pregnancy and breast-feeding
If you are pregnant continue taking <invented name>. Speak to your doctor, because the dose may need to be changed.

If you have taken <invented name>together with an antithyroid medicine to treat an overproduction of thyroid hormones, your doctor will advise you to stop <invented name>treatment when you become pregnant.

If you are breast-feeding, continue taking <invented name>as advised by your doctor. The amount of drug that is excreted into the breast milk is so small that it will not affect the child.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.
It is not expected that <invented name>has any influence on the ability to drive and use machines, because levothyroxine is identical to the naturally occurring thyroid hormone.

Important information about some of the ingredients of <invented name>
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take <invented name>

Always take <invented name>exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist, if you are not sure.

Your doctor will determine your individual dose based on examinations and as well as on laboratory tests. In general, you start with a low dose, which is increased every 2 – 4 weeks, until your full individual dose is reached. During the initial weeks of treatment you will have appointments for laboratory tests in order to adjust the dose.
If your baby is born with hypothyroidism your doctor may recommend to start with a higher dose because a rapid replacement is important. The initial recommended dosage is 10 to 15 micrograms per kg body weight for the first 3 months. Thereafter, your doctor will adjust the dose individually.

The usual dose range is shown in the table below. A lower individualized dose may be sufficient,
- if you are an elderly patient,
- if you have heart problems,
- if you have severe or long-standing thyroid sub-function,
- if you have low weight or a large goitre.

Use of <invented name>	*Recommended daily dose of* <invented name>	
- to treat benign goitre in patients with normal thyroid function	75 - 200 microgram	
- to prevent recurrence of goitre after surgery	75 - 200 microgram	
- to replace natural thyroid hormones, when your thyroid gland does not produce enough - initial dose - maintenance dose	adults 25 - 50 microgram * 100 - 200 microgram	children 12.5 – 50 microgram * 100 – 150 microgram per m^2 of body surface
- to suppress tumour growth in patients with thyroid cancer	150 - 300 microgram	
- to balance thyroid hormone levels, when overproduction of hormones is treated with anti-thyroid medicines	50 - 100 microgram	
- to test thyroid function**	100 microgram: *** 200 microgram (2 tablets) starting 2 weeks before the test 150 microgram: **** Starting 4 weeks before the test 75 microgram (½ tablet) for two weeks, then 150 microgram (1 tablet) until the test 200 microgram: ***** 200 microgram (1 tablet) starting 2 weeks before the test	

** the following information will only be included in the package leaflets of* <invented name>*, 125 microgram, 150 microgram, 175 microgram or 200 microgram:*
<invented name> 125 microgram, 150 microgram, 175 microgram or 200 microgram tablets are not suitable for the lower dose range listed here, but your doctor may prescribe a lower strength of <invented name>tablets.

*** only applicable for the package leaflets of <invented name> 100 microgram, 150 microgram or 200 microgram.*
**** the respective information will only be included in the package leaflet of <invented name> 100 microgram.*
***** the respective information will only be included in the package leaflet of <invented name>150 microgram.*
****** the respective information will only be included in the package leaflet of <invented name>200 microgram.*

Administration
<invented name>is meant for oral use. Take a single daily dose on an empty stomach in the morning (at least half an hour before breakfast), preferably with a little liquid, for example with half a glass of water.

Infants may receive the entire daily dose of <invented name>at least half an hour before the first meal of the day. Immediately before use, crush the tablet and mix it with some water and give it to the child with some more liquid. Always prepare the mixture freshly.

Duration of treatment
Duration of treatment may vary depending on the condition for which you use <invented name>. Your doctor will therefore discuss with you how long you need to take it. Most patients need to take <invented name>for their lifetime.

If you take more <invented name>than you should
If you have taken a higher dose than prescribed, you may experience symptoms such as rapid heart beat, anxiety, agitation or unintended movements. In patients with a disorder affecting the neurological system such as epilepsy, seizures may occur in isolated cases. In patients at risk of psychotic disorders, symptoms of acute psychosis may occur. If any of this happens, contact your doctor.

If you forget to take <invented name>
Do not take a double dose to make up for a forgotten tablet, but take the normal dose the following day. If you have any further questions on the use of <invented name>, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, <invented name>can cause side effects, although not everybody gets them.

You may experience one or more of the following side effects if you take more <invented name>than prescribed, or if you do not tolerate your prescribed dose (e.g. when the dose is increased quickly):

Irregular or rapid heart beat, chest pain, headache, muscle weakness or cramps, flushing (warmth and redness of the face), fever, vomiting, disorders of menstruation, pseudotumor cerebri (increased pressure in the head), trembling, restlessness, sleep disturbances, sweating, weight loss, diarrhoea.

If you experience any of these side effects, contact your doctor. Your doctor may decide to interrrupt the therapy for several days or to reduce the daily dose until the side effects have disappeared.

Allergic reactions to any of the ingredients of <invented name>are possible (see section 6. ‘What <invented name>contains’). Allergic reactions may include rash, urticaria and swelling of the face or throat (angio-oedema). If this happens, contact your doctor immediately.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

Keep this medicine out of the sight and reach of children.

Do not use <invented name>after the expiry date, which is stated on the blister or bottle label and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30° C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What <invented name><strength> microgram contains

- The active substance is levothyroxine. Each tablet contains 25 microgram, 50 microgram, 75 microgram, 100 microgram, 125 microgram, 150 microgram, 175 microgram, or 200 microgram levothyroxine sodium.
- The other ingredients are microcrystalline cellulose (E 460i), pregelatinized starch (E1422), silica colloidal anhydrous (E 551), talc (E 553b), magnesium stearate (E572), indigo carmine Aluminium Lake (E132) (75 and 150 microgram tablets), brilliant blue FCF Aluminium Lake (E133) (125 and 175 microgram tablets), D & C Red no. 27 and 30 Aluminium Lake (175 microgram tablets), Iron oxide Red (E172) (25, 75, 125 and 200 microgram tablets), and Iron oxide Yellow (E172) (25, 100, and 125 microgram tablets).

What <invented name><strength> microgram looks like and contents of the pack

25 microgram: round orange color tablets with score line on one side and “25” debossed on the other side of the tablet. Diameter: 7.0 mm
50 microgram: round white color tablets with score line on one side and “50” debossed on the other side of the tablet. Diameter: 7.0 mm
75 microgram: round violet color tablets with score line on one side and “75” debossed on the other side of the tablet. Diameter: 7.0 mm
100 microgram: round yellow color tablets with score line on one side and “100” debossed on the other side of the tablet. Diameter: 7.0 mm
125 microgram: round brown color tablets with score line on one side and “125” debossed on the other side of the tablet. Diameter: 7.0 mm
150 microgram: round blue color tablets with score line on one side and “150” debossed on the other side of the tablet. Diameter: 7.0 mm
175 microgram: round lilac color tablets with score line on one side and “175” debossed on the other side of the tablet. Diameter: 7.0 mm
200 microgram: round pink color tablets with score line on one side and “200” debossed on the other side of the tablet. Diameter: 7.0 mm

Packed in Aluminium base film with aluminium cover foil and the blisters are packed in respective cartons.

Packed in HDPE bottle pack with a white opaque child resistant closure .

<invented name>is available in packs of 10, 20, 25, 30, 40, 50, 60, 70, 80, 90, 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Strides Nordic ApS
Fuglevangsvej 11,

1962 Frederiksberg C,
Denmark

Manufacturer
Fairmed Healthcare GmbH
Maria-Goeppert-Straße 3
23562 Lübeck
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

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